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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,572	06/07/2001	Yading Wang	460063.93	8128

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EXAMINER

MCCLENDON, SANZA L

ART UNIT PAPER NUMBER

1711

DATE MAILED: 09/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,572

Applicant(s)

WANG ET AL.

Examiner

Sanza L McClendon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47 and 48 is/are allowed.
- 6) ☐ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1-3, 5, 7-9 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al (3,826,678).

Hoffman et al teaches a method for preparation of biocompatible and biofunctional materials. Said method includes radiation grafting a reactable compound onto an inert polymeric substrate and thereafter chemically bonding a biologically active molecule such as heparin. The polymeric substrates can

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be selected from the group found in column 3, lines 54-60, wherein silicone is listed. Said substrate is immersed into a solution of a monomer or monomer mixture in combination with or without organic solvents. Or said substrate can be swelled in the solution of a monomer and/or monomer mixture with or without solvents. Once the substrate has been immersed or swelled the combination can be polymerized via radiation polymerization. The monomers useful in said method can be acrylate compounds, acrylamide compounds, or N-vinylpyrrolidone. It is also taught that molecules that have -OH, -NH₂, or -COOH groups can be used as grafting monomers—see column 3, lines 1-25. The radiation induced polymerization temperature can range from room temperature to about 75 °C above room temperature. Hoffman et al teaches that the irradiation step can be carried out using an average dose rate of 0.25 Mrad/hr or 20,000 curie Co60 for about an hour. This anticipates the claimed polymerization times of the instant invention.

The inventions of claims 1-3, 5, 7-9, and 17-20 are anticipated by the reference.

4. Claims 1-9, 17-19, 21-23, 25, 27-29, 37-39, and 41-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al.

Goldberg et al teaches surface modification of ocular implants, surgical instruments, devices and contact lenses. Said method includes chemical grafting of a plastic substrate with (1) a neutral or ionic water soluble hydrophilic vinylic monomer or salt thereof, (2) a mixture of at least two of said monomers, or a mixture of (1) or (2) with up to 50% by weight of a compound selected from N-vinyl pyrrolidone, 2-hydroxyethylmethacrylate or mixtures of the two. Said plastic substrates can include silicone polymers. Said monomers of (1) can be found in column 8, lines 52-

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60. Said monomers can be used in aqueous solutions in combination with/without a swelling solvent, such as ethyl acetate. Goldberg et al teaches the plastic substrate is pre-soaked in a grafting monomer solution for a period of time sufficient to diffuse the monomers into the substrate surface. Said pre-soaking can be done in such a way that the substrate is first soaked in first monomer solution comprising a hydrophilic monomer to pre-soak the substrate and then placed in a second hydrophilic monomer solution for the subsequent radiation polymerization grafting step. Per examples, the radiation polymerization grafting is carried out at 0.15Mrad gamma radiation at about 500 rads/min. This appears to anticipate the polymerization times. Because Goldberg et al does not specify a polymerization temperature it is assumed to be room temperature and therefore anticipates applicant's polymerization temperatures.

The inventions of claims 1-9, 17-19, 21-23, 25, 27-29, 37-39, and 41-46 are anticipated by the reference.

5. Claims 1-19, 21-39, and 41-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Ottersbach et al (6,001,894).

Ottersbach et al teaches a process for modifying the surface of a polymer substrate by graft polymerization. Said grafting includes pre-treating a polymer substrate with a photoinitiator or thermoinitiator and at least one ethylenically unsaturated monomer, and subjecting said pre-treated substrate to graft polymerization by said at least one ethylenically unsaturated monomer, optionally in the added presence of another ethylenically unsaturated monomer that is the same or different from the other ethylenically unsaturated monomer. Said substrates can be selected from the group found in column 4, lines 43-63 and also the plastic substrates

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found in column 9, lines 19-24, wherein silicone is taught. Said monomers can be found in column 5, lines 15-30. The preferred monomers are monomers that contain carboxyl or caboxylate groups, sulfinate groups, hydroxyl groups, amino or ammonium groups, or phosphate groups. Ottersbach teaches the polymer substrate is (1) pre-treated with a photoinitiator or thermoinitiator and at least one monomer. The initiators can be used in amounts from 0.01 to 40 percent by weight based on the monomer. Said pre-treatment step allows for the monomer and initiator to swell the polymeric substrate which is done for 1 to 15 seconds. Said photoinitiator must be soluble in the monomer for adequate swelling into the polymeric substrate, wherein organic solvents can be used to facilitate solubility. Once pre-treated the substrate can be removed from the monomer and initiator mixture and then irradiated to facilitate graft polymerization. In another embodiment, after the pre-treatment step the swelled substrate can be treated by coating, by conventional techniques, with at least one further ethylenically unsaturated monomer before the polymerization step. When using radiation as the polymerization means, exposure times are usually from 60 to 300 seconds at temperatures from 0 °C to 100 °C. When using heat as the polymerization means, exposure times are generally carried from 1 to 60 minutes at temperatures from 50 to 150 °C.

The teachings of Ottersbach et al appears to anticipate the inventions of claims 1-19, 21-39, and 41-46.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 20 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ottersbach et al (6,001,894).

Ottersbach et al is described in the above rejection. Ottersbach et al fails to expressly teach adhering heparin to the surface of a polymeric substrate (specifically silicone) following the removal of said substrate from the swelling monomer. Ottersbach et al teaches modification of polymer substrates, such as silicone, with monomers that comprise carboxyl or caboxylate groups, sulfinate groups, hydroxyl groups, amino or ammonium groups, or phosphate groups for use in medical applications, such as catheters, blood bags, and contact lenses. Wherein, said functional groups are present after polymerization. The examiner contends that it would have been obvious for one of ordinary skill in the art to adhere heparin, an anti-coagulant for blood, to the surface of the modified polymeric substrates by the Ottersbach method when used in medical applications. The motivation would have been the adequate prevention of blood clotting in/on the medical products produced by the Ottersbach method in the absence of unexpected results and arguments to the contrary.

The inventions of claims 20 and 40 are obvious in view of the teachings of the reference.

Allowable Subject Matter

8. Claims 47-48 are allowed.

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9. The following is an examiner's statement of reasons for allowance:

10. The prior art fails to teach a process for surface modification of a silicone substrate comprising the steps in claim 47. Nor does the prior art teach a process for forming a surface interpenetrating polymer network on a silicone substrate comprising the steps found in claim 48.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanza L McClendon whose telephone number is (703) 305-0505. The examiner can normally be reached on Monday through Friday 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (703) 308-2462. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0657.

Sanza L McClendon
Examiner
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August 21, 2002

James J. Seidleck
Supervisory Patent Examiner
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